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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,986	06/27/2001	Richard James Lewis	14438	1227

7590 12/11/2002

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EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	17

DATE MAILED: 12/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,986	LEWIS ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *11-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 16-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-10 and 16-27 in Paper No. 16 (filed September 30, 2002) is acknowledged. The traversal is on the ground(s) that Groups I-IV are not distinct, they are related to each other and represent one single inventive concept. This is not found persuasive because Groups I-IV lack the same or corresponding special technical features, e.g., the special technical feature of Group I is the specific χ-conotoxin peptides, the specific method of making medicament using the χ-conotoxin peptides, and the specific method of treating diseases using the χ-conotoxin peptides; while the special technical feature of Group II is the particular nucleic acids; the special technical feature of Group III is the particular antibodies; and the special technical feature of Group IV is the particular receptor binding assay using the χ-conotoxin peptides. Groups I-IV are directed to different chemical entities (peptides, nucleic acids, antibodies) and methods, which have different mode of operation or function, and produce different effect, thus, the groups do not have the same technical features. Accordingly, the claims in Group I-IV are not linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept. The requirement is still deemed proper and is therefore made Final.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 24 and 25 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3, 5-10 and 16-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for two χ-conotoxin peptides, χ-MrIA and χ-MrIB having the ability to inhibit a neuronal amine transporter, does not reasonably provide enablement for a χ-conotoxin peptide having the ability to inhibit a neuronal amine transporter but without an identified amino acid sequence; a chimeric peptide comprising the χ-conotoxin peptide and a biologically active peptide; a composition comprising the χ-conotoxin peptide; a method for treatment or prophylaxis of urinary or cardiovascular diseases, mood disorders, pain or inflammation by administering the χ-conotoxin peptide; or a method of making a medicament using the χ-conotoxin peptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-3, 5-10 and 16-27 encompass a χ-conotoxin peptide having the ability to inhibit a neuronal amine transporter (1-3, 5-10); a chimeric peptide comprising the χ-conotoxin peptide and a biologically active peptide (claim 16); a composition comprising the χ-conotoxin peptide (claims 22 and 23); a method for treatment or prophylaxis of urinary or cardiovascular diseases, mood disorders, pain or inflammation by administering the χ-conotoxin peptide (claims 17-21, 26 and 27); or a method of making a medicament using the χ-conotoxin peptide (claims 24 and 25). The specification, however, only discloses cursory conclusions (page 1, lines 3-9; page 1, line 29-page 2, line 1) without data supporting the findings, which state that novel χ-conotoxin peptides and derivatives are useful as inhibitors of neuronal amine transporters of neurotransmitters such as noradrenaline and in the prophylaxis or treatment of conditions such as incontinence, cardiovascular conditions and mood disorders. There are no indicia that the present application enables the full scope in view of χ-conotoxin peptides and a method of treating urinary or cardiovascular diseases, mood disorders, pain or inflammation as discussed in the stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is enabled. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the presence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

The breath of the claims is broad and encompasses unspecified variants regarding χ-conotoxin peptides, chimeric peptides containing χ-conotoxin peptides and the treating conditions for various diseases, which are not adequately described or demonstrated in the specification.

(2). The presence or absence of working examples:

The specification indicates the sequences of two χ-conotoxin peptides, χ-MrIA and χ-MrIB and demonstrates χ-MrIA has the ability to inhibit a neuronal noradrenaline transporter. However, there are no working examples indicating the claimed methods in association with claimed variants.

(3). The state of the prior art and relative skill of those in the art:

The prior art (e.g., U. S. Patent 5,441,985; WO 98/22126; Ardid et al., Fundam. Clin. Pharmacol. 6, 75-82 (1992)) indicates a method of treating lower urinary tract disorder employing an aryloxypropylamine which inhibits noradrenaline (norepinephrine) uptake and has negligible anticholinergic effect; use of an acetylcholine receptor antagonist such as α-conotoxin ImI and MII as a cardiovascular agent; or use of noradrenaline uptake inhibitors such as desipramine for the treatment of chronic pain. however, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on the identities of various χ-conotoxin peptides and the treating conditions for various diseases such as urinary or cardiovascular diseases, mood disorders, pain or inflammation.

(4). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to various χ-conotoxin peptides having the ability to inhibit a neuronal amine transporter; a chimeric peptide comprising the χ-conotoxin peptide and a biologically active peptide; a composition comprising the χ-conotoxin peptide; a method for treatment or prophylaxis of urinary or cardiovascular diseases, mood disorders, pain or inflammation by administering the χ-conotoxin peptide; and a method of making a medicament using the χ-conotoxin peptide. The specification only indicates the amino acid sequences of two χ-conotoxin peptides, χ-MrIA and χ-MrIB (page 3, lines 5-15), cites various possible modifications for derivatives of χ-conotoxin peptides (pages 4-11), and shows χ-MrIA has the ability to inhibit a neuronal noradrenaline transporter but negligible activity as an anticholinergic agent, a sodium channel blocker or an inhibitor of dopamine transporter (Examples 1-6). However, the specification does not identify any derivatives of χ-MrIA or χ-MrIB, nor demonstrates any χ-conotoxin peptide other than χ-MrIA having the ability to inhibit a neuronal amine transporter. The specification has not demonstrated the use of any χ-conotoxin peptide for treating various diseases such as urinary or cardiovascular diseases, mood disorders, pain or inflammation. There are no working examples indicating the claimed methods in association with claimed variants. The specification fails to provide the treating conditions such as the dose and the time for various diseases cited, nor the effect of the treatment. Since the specification fails to provide sufficient guidance on the identities of various χ-conotoxin peptides and the treating conditions on various cited diseases, it is necessary to have additional guidance on the χ-conotoxin peptides and to carry out further experimentation to assess the effects of these χ-conotoxin peptides.

(5). Predictability or unpredictability of the art:

The specification indicates χ-MrIA has the ability to inhibit a neuronal noradrenaline transporter (Example 1), and cites the prior art (U. S. Patent 5,441,985) shows compounds which inhibits noradrenaline uptake and has negligible anticholinergic effect are useful for treating lower urinary tract disorder (page 2, lines 3-9). However, the compounds cited in the art are small organic molecules, which are structurally different from χ-conotoxin peptides. Furthermore, the specification does not demonstrate the treating conditions for various diseases using a χ-conotoxin nor the effect of the χ-conotoxin. Since the treating conditions are not sufficiently described, the outcome of the claimed method is highly unpredictable.

(6). Nature of the Invention

The scope of the claim includes various χ-conotoxin peptides and using χ-conotoxin peptides in treating various diseases such as urinary or cardiovascular diseases, mood disorders, pain or inflammation, however the specification has not demonstrated the treatment of these pathological conditions using an identified χ-conotoxin peptide. Thus, the disclosure is not enabling for reasons discussed above.

In summary, the scope of the claim is broad, while the working example does not demonstrate the claimed variants, and the guidance and the teaching in the specification is limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of various χ-conotoxin peptide in treating diseases.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3, 4, 16-21 and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 3 and 4 are indefinite because of the use of the term "one or more amino acid deletion, additions, substitutions or side chain modifications". The term "one or more amino acid deletion, additions, substitutions or side chain modifications" renders the claim indefinite, it is unclear which amino acids are deleted, added, substituted or modified at side chains, and what amino acid sequences are obtained after modification. Claim 3 is also indefinite as to citing "O" in SEQ ID NO:1 or 2, it is not clear what amino acid "O" represents. Claim 4 is included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which it depends.

6. Claim 16 is indefinite because of the use of the term "a chimeric peptide comprising a segment of a naturally occurring χ-conotoxin peptide and a segment or sequence of another biologically active peptide or protein, such that the resultant χ-conotoxin peptide possesses an activity associated with said other peptide or protein". The term "a chimeric peptide comprising a segment of a naturally occurring χ-conotoxin peptide and a segment or sequence of another biologically active peptide or protein, such that the resultant χ-conotoxin peptide possesses an activity associated with said other peptide or protein" renders the claim indefinite, it is unclear which biologically active peptide or protein is intended, which segment of the χ-conotoxin peptide or the other peptide is used, whether the segment of the χ-conotoxin peptide or the other peptide is still biologically active, and which activity the resultant χ-conotoxin peptide possesses.

7. Claims 17-21, 26 and 27 are indefinite because the claims lack essential steps in the method of treating urinary, cardiovascular diseases, mood disorder, pain or inflammation. The omitted steps are: the method of administration and the outcome of the treatment. Claims 18-21 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

8. Claims 24 and 25 provide for the use of χ-conotoxin but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

9. Claim 26 and 27 are indefinite because of the use of the term "diseases or conditions". The term "diseases or conditions" renders the claim indefinite, it is unclear which disease or condition is intended.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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December 10, 2002

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